Plan Overview

A Data Management Plan created using DMPTuuli

Title: Building conceptualization and understanding of momentary fatigue and activity-related fatigability in daily life for people with multiple sclerosis (EMA-FAMS)

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Funder: The Research Council of Finland (former The Academy of Finland)

Template: Research Council of Finland

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Project abstract:

Multiple sclerosis (MS) is a progressive autoimmune and neurodegenerative disease. One of the major symptoms of MS is fatigue which interferes individually with daily life activities and declines performance during tasks. Measuring associations between fatigue and activity performance (i.e., activity-related fatigability) in real-life situations remains yet to be fully explored. The momentary fatigue and activity-related fatigability in daily life for people with multiple sclerosis (EMA-FAMS) study aims to conceptualize and evaluate momentary fatigue and activity-related fatigability in real-life situations for persons who struggle with fatigue in their everyday lives. The study will be organised by LAB University of Applied Sciences, Lahti, Finland. The findings of EMA-FAMS have the potential to discover new ways of understanding how fatigue and fatigability affect a person's daily living.

ID: 25247

Start date: 01-09-2024

End date: 31-08-2028

Last modified: 26-06-2025

Grant number / URL: 360087

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Building conceptualization and understanding of momentary fatigue and activity-related fatigability in daily life for people with multiple sclerosis (EMA-FAMS)

1. General description of data

1.1 What kinds of data is your research based on? What data will be collected, produced or reused? What file formats will the data be in? Additionally, give a rough estimate of the size of the data produced/collected.

Data is collected for this project according to project's research plan. Data will be collected in three types:

1) Literature review data will be based on previously published studies. The size of the data is approximately < 10 MB. Data formats are .xlsx, and .csv. Possible programs designed to conduct data collection for the literature review will be used (e.g., Covidence).

2) Interview data will be based on focus group interviews of participants. The size of the data is approximately > 10 MT. Interview file formats are .mp3/.mp4 and interview transcripts .txt, .odt., .doc, or .xlsx. Data consists of generally accepted formats and will be analyzed using a qualitative statistical program (e.g., ATLAS).

3) A multilevel data frame will consist of several self-reported and objective data using baseline clinical and self-reported assessments, diary surveys and accelerometer (thigh-worn and wrist-worn devices) data. Data consists of generally accepted formats, which will be processed and analyzed using statistical programs such as STATA or R. The size of the data is approximately > 10 MT. File formats are .txt, .csv,.dta, .r, and/or .rdata.

1.2 How will the consistency and quality of data be controlled?

The consistency and quality of the data will be controlled by following the established data collection protocols (for researchers and participants) at the LAB University of Applied Sciences (LAB). The quality controller is the PI of the project. During the data collection, all researchers of each study site (LAB, Finnish Neuro Society, University of Jyvaskyla) will follow the agreed protocols. If deviation occurs, a study diary will be used to report such events.

Datasets will be organised cordially and will include a readme file for each designated folder. The responsibility of data quality control will be for the PI of this project in collaboration with each researcher gathering data from each recruitment site. For data quality, a study protocol will be written for researchers to follow a similar procedure during recruitment and data collection processes.

Qualitative data (e.g., transcription of the audios of the interviews) and quantitative data (e.g., saving the data from questionnaires) will be double-checked by two researchers in the project.

Only responsible PI and researchers named to the project are allowed to access the source data during the project. This ensures that the original raw data cannot be accidentally or intentionally manipulated. When transferring digitally coded and pseudonymized data, data is secured with passwords. When handlining and transferring paper-based coded and pseudonymized data, the material is secured in a locked locker for each study site and only given to the researchers named to the project.

When merging the data into a dataset, the transfer and its accuracy will be double-checked by two researchers within the project. In all conversions, the original information content will be ensured

Training sessions will be organized for the researchers conducting the research phases in the project to ensure the quality of the data.

2. Ethical and legal compliance

2.1 What legal issues are related to your data management? (For example, GDPR and other legislation affecting data processing.)

As this project is defined as a medical research project due to its nature of collecting information related to participant's health, symptoms and personal or sensitive health information, the basis for processing personal data is in accordance with Section 21 a § of the Finnish Medical Research Act, the public interest, and the public health interest (Articles 6.1.e and 9.2.j of the EU General Data Protection Regulation) for the essential processing activities related to the conduct of the research, and compliance with a legal obligation and the public health interest (Articles 6.1.c and 9.2.j of the General Data Protection Regulation) for safety reporting and other notifications to authorities. A medical research ethical approval will be applied from the Ethics Committee of the Helsinki University Hospital before the recruitment process commences.

This study will follow the guidelines of the Finnish National Board on Research Integrity, good scientific practice, and current National legislation and EU regulations. Subjects included in this study will be informed and they will sign a consent following the GDPR guidelines. Participants will be provided with the following information: a briefing on the purpose of the study, information sheets, potential risks and benefits of the study, and the rights of the participant. Consent will also include participants' right to

decline to participate at any point in the study, the definition of anonymized data, and the confidentiality of the data. Consent will also include the participant’s permission to use the anonymized data for research and educational purposes after the study.

The following personal data will be processed: direct identification information (name, address, phone number, city or town of residence, email address), personal characteristics (gender, age, educational background, work/study situation, type of residence, living situation), and health information (perceived fatigue, perceived fatigability, underlying conditions, current regular medication, mood, use of substances/stimulants, daily activities, quality of life, and cognition, walking, and sit to stand tests) will be collected. Also, MS-related health information will be collected including year of onset of initial symptoms, year of diagnosis, type of MS, disease severity, relapses in the past 30 days, and MS medication.

For researchers, the ICMJE (International Committee of Medical Journal Editors) recommendations for defining the role of authors and contributors will be followed.

2.2 How will you manage the rights of the data you use, produce and share?

LAB has the ownership of the data and rights of use. For collaborators named in this project, the collaboration and non-disclosure agreements will be signed with LAB. The intellectual property of the data generated will remain with the PI and LAB.

During the data analysis, coded pseudonymized data will be accessible only by the relevant researchers affiliated and contracted to the project within LAB, the University of Jyvaskyla, and the Finnish Neuro Society. Data can be accessed and shared via CSC Sensitive Data services during the project timeline. If necessary, permission to use coded pseudonymized data may be granted to a researcher who may change their employer during the project by a separate agreement. The data will not be shared outside the EU.

The project will not use any data which is covered by the Copyright, Designs and Patents or any other similar legislation.

3. Documentation and metadata

3. How will you document your data in order to make the data findable, accessible, interoperable and re-usable for you and others? What kind of metadata standards, README files or other documentation will you use to help others to understand and use your data?

At the end of the project, the direct identifiers of the registered participant and the code key file will be retained until the end date of the study (August 31, 2028). Upon the conclusion of the study, the direct identifiers of the registered participant and the associated code key file will be destroyed, and the coded research data will be anonymized by removing or replacing possible indirect or direct identifiable information, whereas possible. The anonymized data will be stored for 15 years after the conclusion of the study at LAB.

After the research project, the PI of this study will ensure that all data is transferred to LAB secure digital storage and all data will be deleted from the secure storage domains of the CSC SD services, University of Jyvaskyla, and the Finnish Neuro Society. Data will be anonymized by deleting the key code and all direct personal identifiers from the datasets and possibly reshaping variables into metadata-level (e.g., categorizing variables). An open research data storage service may be used by the recommendation of LUT Universities in the IDA Research Data Storage Service if anonymization is successful. Anonymized data may be shared for research and educational purposes through separate material and data transfer agreements between organizations. Anonymized data will not be shared if it compromises the privacy of the participants.

All documentation during the project and metadata dataset after the project will include a description file (readme-file) to help navigate the data in question.

4. Storage and backup during the research project

4.1 Where will your data be stored, and how will the data be backed up?

During the project, the use of safe and secure digital storage services (e.g., the internal hard drives) provided, maintained, password-locked, and backed up by LAB, University of Jyvaskyla's, and Finnish Neuro Society’s IT department will be utilized. CSC´s Sensitive Data services will be used to store and share data among the researchers named to the project during the data collection and data analysis phase. Background and health information will be collected digitally via a remote method through a separate service provider, such as a platform specialized in health data (e.g., REDCap) using universities IT support. The data will be collected in coded form, without direct identifiers of the data subject. After the data collection is completed remotely, data is transferred to CSC Sensitive Data services. Paper-based data will be stored in a locked locker at each study when needed during the data collection and data analysis phase.

4.2 Who will be responsible for controlling access to your data, and how will secured access be controlled?

The right to access the data is controlled by the PI of the project and responsible institute LAB. During the project data collection phase, technical access control is provided by each study site's IT department for only the designated researchers named to collect data within each recruitment site. Each researcher is bound by confidentially agreement.

5. Opening, publishing and archiving the data after the research project

5.1 What part of the data can be made openly available or published? Where and when will the data, or its metadata, be made available?

After the research project, sensitive parts of the data will be anonymized, whenever possible. Anonymized data may be shared for research and educational purposes through separate material and data transfer agreements between organizations. Anonymized data will not be shared if it compromises the privacy of the participants. An open research data storage service may be used by the recommendation of LUT Universities in the IDA Research Data Storage Service, if anonymization is successful and the use of the data is based on an agreement with LAB. A minimum of data description will be published as open access (Qvain) and access to anonymized data after the project can be applied from LAB.

5.2 Where will data with long-term value be archived, and for how long?

The project will store data in LAB. If possible, the data can be stored inthe IDA Research Data Storage Service if anonymization is possible. The anonymized data will be stored for 15 years after the conclusion of the study.

6. Data management responsibilities and resources

6.1 Who (for example role, position, and institution) will be responsible for data management?

The PI of the project will be responsible for data management. Other researcher named in this project from each recruitment sites (LAB, Finnish Neuro Society, University of Jyvaskyla) will have an assistive role to manage and maintain the data management activities.

PI of the project is responsible for implementing the DMP and ensuring its revision in a regular update of 6-month periods from the start of the project. PI will be responsible for the data after the project has ended.

6.2 What resources will be required for your data management procedures to ensure that the data can be opened and preserved according to FAIR principles (Findable, Accessible, Interoperable, Re-usable)?

No other resources will be needed other than the resources required to produce the data. FAIR principles are followed.